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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,840	11/06/2000	John A. Drewe	1735.0410002/RWE/BEC	8076

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Sterne Kessler Goldstein & Fox PLLC
Attorneys at Law
Suite 600
1100 New York Avenue N W
Washington, DC 20005-3934

EXAMINER
ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
1625	21

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/704,840	Applicant(s) SASSI, THOMAS PATRICK	
	Examiner Binta M. Robinson	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☒ Claim(s) *42,44,45,63-65,78,80,81,92 and 93* is/are allowed.

6)☒ Claim(s) *1,5,26-28,30,32,64,65,79 and 84-90* is/are rejected.

7)☒ Claim(s) *33-38,40,41,66-72,76,77,82,83 and 91* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *19* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are Claims pending in the application are 1,5-7,9,13,14,16,18,21,25-28,30,32-38,40-42,44-47,50,51,53,54,57,60,63-72 and 75-93..
Continuation of Disposition of Claims: Claims withdrawn from consideration are Claims withdrawn from consideration are 6,7,9,13,14,16,18,21,25,46,47,50,51,53,54,57,59 and 60..

Detailed Action

The Restriction requirement at paper no. 7 is made FINAL.

(old rejections)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, for reasons of record at paper no. 15 because the specification, does not reasonably provide enablement for the method of treating all of the various cancers. No drug can treat all of these cancers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to ***In re Wands***, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the

invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, the treatment of a wide range of cancers with a compound of claim 1 is being claimed. In terms of the nature of the invention which is the second Wands factor, these compounds are useful in the treatment of various cancers. .In terms of the fifth Wands factor, the capase potency ranges from 7 which is poor to 364 which are great. There are massive differences in caspase potency for small changes in structure. For example, compound 97 has a 3 bromo instead of a 2 bromo and a methyl on the 4H-indolo ring. However, the caspase potency compound 7 whereas it is 364 for compound 95. The level of predictability regarding caspase potency is low. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test compounds for their affects on the specific diseases claimed. The applicant must show tests results for the cancers claimed involving specific cell lines. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

Claim 41 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 66. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 66 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 67. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 67 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 66. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 68 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 69. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 69 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 68. When two claims in an application are duplicates or else are so close in

content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 70 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 69. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 71 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 41. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 72 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 41. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 26, and 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of treating all inflammation diseases or cancers related to a disorder responsive to the induction of apoptosis in an animal suffering therefrom or all drug resistant cancers, orR10 and R11, or R11 and R12 of the compound in claim 46 coming together to form all heteraryl or optionally substituted heterocyclic groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to ***In re Wands***, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in ***Ex parte*** foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1)the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the first Wands factor of breadth, the treatment of all diseases responsive to the induction of apoptosis in an animal with a compound of formula I are being claimed. In terms of the nature of the invention which is the second
Wands factor, these compounds are useful as activators of caspases and inducers of apoptosis. In terms of the sixth Wands factor, the amount of direction provided by the inventor is poor, because the applicant does not test compounds for their affects on the specific diseases claimed. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

(new rejections)

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim(s) 1, 5, 26, 27, 30, 32, 79 84-90 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 1, 5, 26, and 79 in part, at paper no. 13C, the phrase "inflammation" is indefinite. It is unclear as to which inflammation diseases the applicant is referring to.

B. In claim 27, line 2, page 5, of the amendment at paper no. 13C, and claim 90, the term "cancer" is indefinite. What cancer is the applicant claiming?

C. In claim 32, lines 2-3, page 115, and all other occurrences of this term in claims 33the phrase "cancer chemotherapeutic agent" and "pharmaceutically acceptable salt of said agent" are indefinite. What cancer chemotherapeutic agents are the applicant claiming?

D. In claim 30, lines 1-2, page 115, the phrase "drug resistant cancer" is indefinite. What drug resistant cancers is the applicant claiming?

E. In claim 64, lines 2-3, page 131, the term " cancer chemotherapeutic agent, or a pharmaceutically acceptable salt of said agent" is indefinite. Which cancer chemotherapeutic agent or salt thereof is the applicant claiming?

F. In claim 65, line 9, page 12 of the amendment at paper 10/B, the terms "Herceptin ® ", and "Rituxan ®" are indefinite because they are trade names.

Claims 33-38, 40-41, 66-72, 76-77, 82-83, 91, are objected to because they are based on a rejected claim and/or duplicates of another claim.

Claims 42, 44, 45, 63-65, 75, 78, 80, 81, ~~92 and 93~~ appear to be allowable as they read on the examined subject matter.

Response to Applicant's Remarks

The applicant alleges that the amendments have overcome the rejections at paper no. 15. However, applicant only adds new claims 90-93 rather than overcoming the rejections at paper no. 15.

The IDS at paper no. 19 has been considered.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Alan L. Rotman

ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

BMR
5/23/03